



BCR TKA Designs: A Comprehensive Review of the Literature

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Abstract

Background: More than 20% of total knee replacement (TKR) patients reveal to be unsatisfied by their implant; an unacceptably high rate nowadays. The main underlying reason of this failure can be attributed to abnormal kinematics, poor proprioceptive outcomes and discomforts associated to the current standard arthroplasties. While in the latter the anterior cruciate ligament (ACL) is sacrificed, a diametrically opposed approach called bicruciate retaining (BCR) TKR spares both cruciate ligaments. Although this anatomical approach is supported by many publications in terms of knee motion, patient preference and joint feeling, it failed to solidly establish on the market, mainly due to design flaws and a highly challenging surgical procedure.

Objectives: The aim of this review is to describe in detail the most important BCR designs ever developed and present their reported clinical limitations. A special focus is set on the most relevant weaknesses of these implants, in the attempt to finally highlight the key features of a new ideal BCR design and reveal possible solutions to the current technical challenges related to ACL retention.

Methodology: For this purpose, a comprehensive literature research was performed through Embase, Scopus, Science Direct, Medline databases, arthroplasty journals, books and additional sources.

Conclusion: From the collected data, it clearly emerges that BCR designs have significantly evolved over the years. The resulting contemporary BCR prosthesis succeed in solving many past design flaws, however the early results suggest that further improvements are still required to reduce the dissatisfaction rate after total knee arthroplasty (TKA) once and for all.

Key-words: Bicruciate Retaining (BCR); Total Knee Replacement (TKR); Total Knee Arthroplasty (TKA); Anterior Cruciate Ligament (ACL); Design..

Introduction

1. Current TKAs and their limitations

Nowadays, standard procedures for TKR in patients with advanced osteoarthritis (OA) and rheumatoid arthritis (RA) of knee joint, consist in the insertion of posterior cruciate substituting (PS) or cruciate retaining (CR) prosthesis.[1,2] Both implants require ACL sacrifice (Fig. 1).

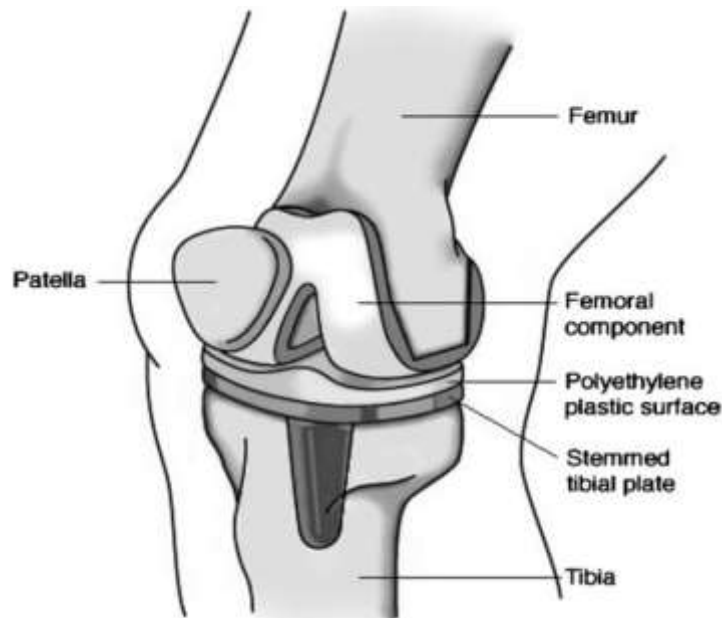


Figure 1: a standard total knee arthroplasty TKA and its components.[3]

Although PS and CR total knee replacements are well established worldwide, approximately 20% of patients who undergo TKA are unsatisfied, a consistently higher percentage than discontent patients after total hip arthroplasty (THA).[4-7] This is surely correlated to the higher expectations of young and active people experiencing TKR.[8] According to dr. Kurtz et al., a 17-fold increase in the number of TKAs in the 45-54 age category, from 59,077 procedures in 2006 to 994,104 procedures in 2030 is anticipated.[4] This young generation aims for a return to demanding activities such as cycling, running and sports trainings and competitions, even at high level, all exercises that strongly require a close to normal knee kinematics and proprioception. However, the current PS and CR prosthesis show many limitations in this direction. On the contrary, unicompartmental knee arthroplasty (UKA), which spares both ACL and PCL, has demonstrated kinematic and proprioceptive outcomes that more closely resemble the normal knee.[9-11] Therefore, it is clear that bicruciate retention might be the key to reduce the gap with satisfaction rates after THA.[11]

In this optics, a different approach called bicruciate retaining (BCR) TKA offers a promising solution. BCR TKA, as the name suggests, is a specialized prosthetic implant which preserves both ACL and PCL. BCR prosthesis belongs to the “anatomical approach” aiming to recreate the physiological anatomy of knee joint, juxtaposed to CR and PS designs which focus on functionality instead, hence belonging to the so called “functional approach”.[12,13]

2. BCR TKA advantages

Bicruciate retaining designs are supported over ACL-sacrificing ones by many reports in literature. In terms of kinematics, [14-20] BCR TKA demonstrates more normal posterior femoral roll back during deep bending, compared to a CR TKA, which shows anterior femoral movement on flexion and exaggerated medial condyle translation on deep knee bend instead.[21-23] Anteroposterior laxity has also been shown to be closer to normal in BCR TKA than CR and PS TKA.[21,24] Stiehl et al reported a femorotibial contact close to the tibial midline in full extension in BCR designs similarly to healthy knee, while for CR implants the contact was significantly posterior.[14] Several studies univocally prove satisfying performance of BCR arthroplasties in gait and stair climbing analysis, where CR TKAs revealed extensor moment weakness with forward leaning and decreased stance phase knee flexion, typical of ACL-deficient knees.[14,15,22,25-28]

At the same time, it has been shown that in absence of ACL, the PCL and collateral ligaments are abnormally loaded through the ROM, leading to a reduction in femoral rollback by an average of 36% and a 15% loss in extensor efficiency.[29] In posteriorly stabilized PS arthroplasties, both cruciate ligaments are extracted and compensated by a post-cam mechanism. This design demonstrated less abnormal kinematics than PCL-retaining TKAs², but still Mahoney et al. shown a 12 % loss in rollback and an 11 % decrease in extensor efficiency.[29] Another kinematic study performed by Stacey M. Acker et al., assessing deep flexion daily activities performed by Asian patients, demonstrated a significantly higher femoral external rotation in PS knees with respect to the normal 20-30° range of normal joints. This is attributable to the absence of ACL constraint during knee motion in PS arthroplasties. [29,31] Furthermore, these functional designs are constraining and forcing the knee motion alone, resulting in higher stresses at the bone-implant interface and therefore possible prosthetic failures. On the other hand, a design which replicates the normal anatomy and spares the knee-stabilizing soft tissues will allow for physiological force transmission through ligaments, reducing the stresses on the implant.[32]

In terms of proprioception, several recent researches reported superior outcomes in patients undergoing BCR TKAs rather than CR or PS procedures.[2,3,9,33-35] In addition to kinematics and proprioception and significantly linked to them are the patient reported outcomes (PROs), describing the patient satisfaction and feelings about the implant. In this context, dr. Pritchett reported that in 440 patients undergoing bilateral TKA with different prosthesis, with a minimum of 2-year follow-up, 89.1% preferred a BCR design in one knee to a PS in the other.[2] In a similar study, Pritchett, analyzing 50 patients, could show that 70% percent of them preferred the BCR knee, whereas only 10% preferred the posterior cruciate-retaining knee.[28] In addition, reduced joint awareness was observed in patients receiving a contemporary BCR implant with respect to PS prosthesis.[36]

Last but not least, Lombardi et al. found that if an intact ACL is removed during TKA the patient will have poorer postoperative results and more restricted ROM compared to patients who had an absent or dysfunctional ACL at operation time, strongly justifying a BCR arthroplasty for the former.[11] All these data firmly support BCR approach for patients with intact ACL, representing more than half of patients with knee OA undergoing TKA,[37] or at least with a functional anterior cruciate, findable in roughly 78% of knees at the time of TKA, according to Johnson et al.[38]

3. BCR TKA disadvantages

Unfortunately, bicruciate retaining TKA doesn't come with advantages only. Some critical drawbacks have limited its wide-spreading on the market and made it outpaced by CR and PS techniques. Although BCR limitations will be discussed in details further on in this review, the main disadvantages carried by this approach are anticipated here.

The biggest drawback of BCR TKA is the more challenging knee surgery with respect to other designs such as PS and CR.[10,32-34,39,40] Indeed, in order to spare the ACL, the tibia eminence must be preserved and this make it impossible to sublunate the tibia intraoperatively, therefore narrowing the surgical space.[11,32] At the same time, the anatomical joint line (on average 3° of varus) should be restored, meaning that the exact amount of cartilage and bone resected should be supplemented by the implant.[41] Any significant discrepancy, will alter the normal kinematics and ligament tension. During BCR TKA, accurate balancing of the knee through the ROM is vital, but extremely challenging at the same time.[42,43] Hence, fracture of the tibial eminence and rupture of the ACL are not infrequent intraoperatively under not experienced

hands, making the surgical technique not easily reproducible.[39,43-45] Given the narrow space available intraoperatively, the size of fixation pegs or keels in the tibial component is constrained, while the application of a long stem as in PS and CR is out of question.[11,46] This might result in tibial tray loosening.[33,47,48] At the same time, as the tibial eminence must be retained, instead of fully covering the bone surface, the tibial baseplate must have a central cutout and a narrow bridge connecting the medial and lateral plateau, that therefore limits the bone-implant contact area, favoring instability and fatigue fractures of the anterior bridge.[46,49-52] Furthermore, patient selection criteria is considerably stricter for BCR TKA rather than bicruciate sacrificing knee replacements. It's obvious that ligaments must be present and functionally intact, a requirement not always fulfilled by elderly patients with advanced OA or RA. Concurrently, varus, valgus deformity and flexion contracture must be minimal.[12,39,53] Last but not least, BCR TKA is not only technically but also economically demanding. Design and development of these implants is usually associated with additional costs.[1]

To sum up, BCR arthroplasty represents a complex reality with weaknesses but strong benefits at the same time, that could finally bring the relatively high dissatisfaction rates after TKA to an end. The goal of this report is to review in detail the major BCR designs from the historical to the contemporary ones, aiming for a deep understanding of their limitations in order to set some key design specifics which could help to overcome the latter.

Materials and Methods

1. Research strategy

A comprehensive literature research was performed through 5 main online databases: Embase, Science Direct, Medline, Scopus and Google scholar. Arthroplasty journals, orthopedic books, additional material provided by Tarabichi center (AZHD) and other sources were also consulted and included into this work. The research strategy did not follow a standard protocol because, contrarily to a conventional systematic review, this paper doesn't focus on a specific topic or aspect only, but covers a huge variety of themes, a significant number of different BCR designs, each one described in as much detail as possible, making it impossible to adopt a single, unique research plan. However, a personalized strategy was performed during databases consultation, to make the review as systematic as possible. Initially a broad investigation of BCR arthroplasties was performed in order to obtain basic knowledge about this field that was then exploited for

the Introduction, Discussion and Conclusion paragraphs. Examples of search strings employed are: (BCR OR bicruciate retaining OR bi-cruciate retaining) AND (TKA OR TKR OR total knee replacement OR total knee arthroplasty OR implant OR implants OR prosthesis) AND (review OR systematic review); (ACL OR anterior cruciate ligament OR anterior cruciate) AND (preserv* OR spar* OR retain*) AND (TKA OR TKR OR total knee replacement OR total knee arthroplasty OR implant OR implants OR prosthesis). In a subsequent step, more precise information about BCR designs was searched, with the aim to find all the major implants that have ever been developed until now. For this purpose, orthopedic books revealed to be more suitable than journal papers. The main research step comes now. After the individuation of all main BCR designs in TKA history, for each one a methodical research was performed in the databases, through every paper reference and images found online. For the contemporary BCR implants, the company website was consulted aiming to find product information and the design rationale.

2. Inclusion/exclusion criteria:

Every study presenting BCR TKA approach was assessed in first place. Since, a basic knowledge of the field was initially sought, priority and preference was given to reviews and TKA books until collected data were considered enough by the author. In a second place, papers regarding each separate BCR design was read and evaluated. In this phase, studies not regarding directly the BCR design under consideration, in a non-English language, without an open institutional access or with low level of evidence (grey literature, conference abstracts, case reports and expert opinions) were excluded. On the other hand, every source providing reliable additional data to the already collected one was taken into consideration, resulting in a wide range of references. In this way, double checks could be performed between different publications to confirm the validity of most of the findings and therefore increase the solidity of the data provided in this work.

Results

1. History of BCR TKA designs:

The end of 1960s and beginning of 1970s represented a turning point for TKR. Huge excitement soared in the field after the introduction of high density polyethylene (HDPE) in 1963 and the first application of bone cement PMMA for implant fixation in 1960.[12,54] In this highly motivating atmosphere, several new

TKA designs of both anatomical and functional approach were developed. In this review, we will focus only on the anatomical category, particularly on BCR implants. A chronological overview of these is presented below, dwelling on major design features, clinical outcomes and limitations. The prosthesis will be divided in two families according to the year of commercial release: historical and modern BCR designs (Fig. 2). While the contemporary implants will be described in details, the historical designs will be summarized in tables, in order to relieve and efficiently organize the information load and therefore smooth the reading process. For these old prosthesis, the “main design weaknesses” column refers to the initial proposed version, unless otherwise stated.

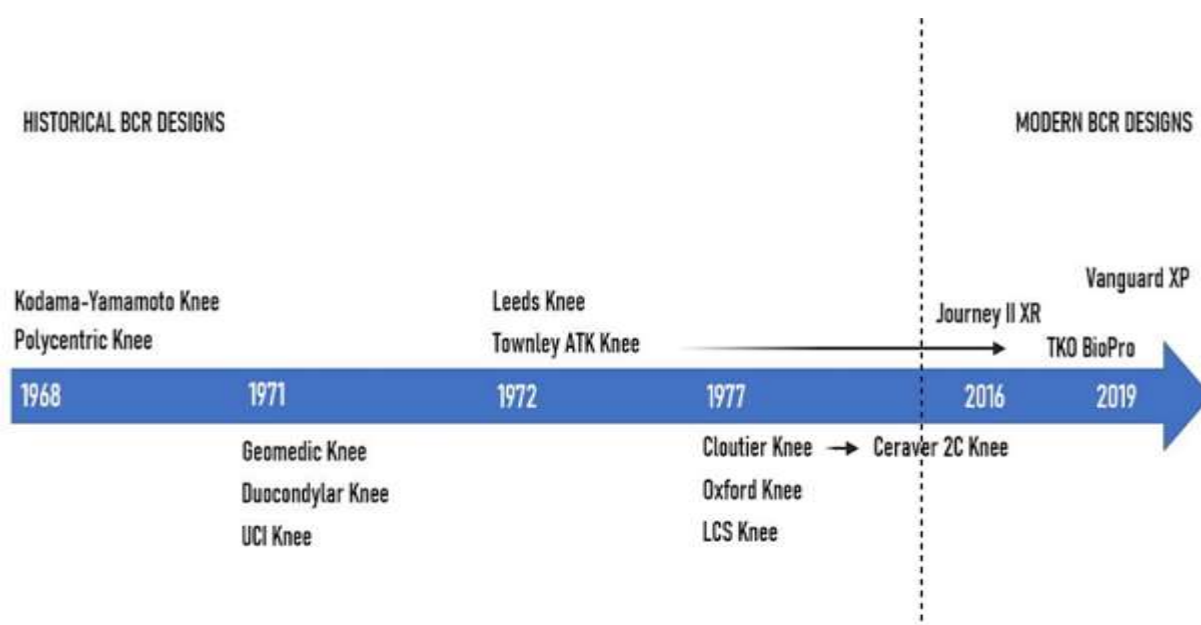


Figure 2: chronological representation of the historical and modern BCR designs assessed in this review.

2. Historical BCR designs:

Polycentric Knee, dr. Frank Gunston, 1968

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
The cemented Polycentric Knee is recognized as the first bicompartamental knee arthroplasty without relying on any hinge, while retaining both cruciate and collateral ligaments instead.[12,55-57]	<ul style="list-style-type: none"> - comprised of two unicompartamental implants (Fig. 3A,3B). - semicircular Co-Cr femoral components. - HDPE tibial concave runners. - patellar and femoral groove preserved. 	<ul style="list-style-type: none"> - poor postoperative ROM (8.4-101°) (2 years f.u.*).[55] - failure rate of 11.8%, with loosening being 4.2% (3.3 years f.u.).[58] - 34% of knees classified as failures. The main causes reported as instability and loosening (10 years f.u.).[59] 	<ul style="list-style-type: none"> - too minimalistic design. - lack of anterior bridge led to implant misalignment. - narrow femoral components resulted in high contact stresses on PE inserts. - lack of metal backing in tibial component.

*f.u. stands for follow-up.



Figure 3: Gunston's Polycentric Knee prosthesis (A)[57]. Drawing of Gunston's Polycentric Knee prosthesis implanted (B).[54]

Kodama-Yamamoto Knee, Kodama and Yamamoto, 1968

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses**
<p>In 1968, the first cementless total condylar knee was invented by Kodama and Yamamoto at Okayama University, Japan.[12,13,54,60-63] The Kodama-Yamamoto Knee will then be called Mark I and subsequently develop in Mark II, Mark III and finally in the modern “New Yamamoto Mico Fit Knee”, manufactured and distributed by Corin company.</p>	<ul style="list-style-type: none"> - COP alloy (Co, Cr, Ni, Mo, C and P) femoral component with anterior flange. - horseshoe shaped HDPE tibial component, allowing the retention of ACL and PCL (Fig. 4A). - slightly dished tibial surface. - two anterior staples in the tibia and fins on the femur for improved fixation. <p>Subsequent modifications :</p> <ul style="list-style-type: none"> - multi-radius femoral profile (Mark II, Fig 4B). - HDPE patellar component (Mark III, Fig. 4C). - larger tibial tray with three layer peg for fixation (Mark III). 	<ul style="list-style-type: none"> - poor postoperative ROM (87°) (1-4 years f.u.).[62] - implant instability, high aseptic loosening and sinking prevalence, restricted ROM (10 years f.u.).[63] - 4.4% of knees showed aseptic loosening. Poor ROM (96.5°) (2-7 year f.u.). [64] 	<ul style="list-style-type: none"> - symmetrical femoral condyles. - symmetrical femoral flange. - lack of metal backing in tibial component. - poor tibial fixation components. - symmetrical tibial plateaus. - non-anatomical, symmetrical tibial component.

** Referred to Mark III design; as consequence Mark I and II come with more limitations than the ones reported

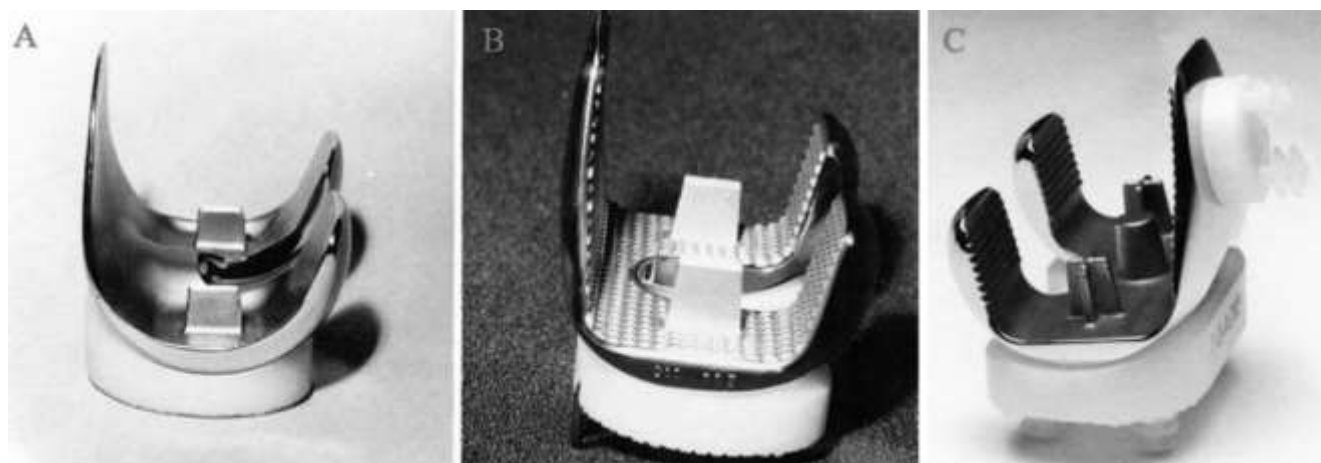


Figure 4: Mark I implant (A). Mark II implant (B). Mark III implant (C).[63]

Geomedic Knee, dr. Coventry, Averill, 1971

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
<p>Designed in 1971 at Mayo clinic, Minnesota, by a team of engineers and physicians led by dr. Coventry and mr. Averill, the so called Geomedic Knee is considered as the first cemented BCR bicondylar knee replacement.[12,13,65]</p>	<ul style="list-style-type: none"> - vitallium femoral component and HDPE tibial component comprised of two parts joined by a thin anterior bridge. - pins and depressions in the femoral side to allow for stable fixation. - two spherical condyle surfaces of radius 23.8 mm articulating against highly conformal, concave bearings on the tibial side, aiming for a PE wear reduction. <p>Subsequent modifications[66-69]:</p> <ul style="list-style-type: none"> - higher sagittal radius in the tibial component to decrease congruity and constraint. - femoral flange. - anterior tibial dovetail peg to improve fixation. - deeper femoral bridge to avoid patellar impingement. 	<ul style="list-style-type: none"> - 16.3% of failures and 9.8% of tibial loosening (3.3 years f.u.).[58] - radiolucent lines at the tibial bone-cement interface present in 62% of implants (sign of implant loosening) led to 18% prosthesis removal. 13-years survival rate reported to be 58% (11 year f.u.).[70] - tibial loosening in 37% of knees (58 months f.u.).[71] - poor postoperative ROM (<90°), 11.8% of tibial loosening. Radiolucent lines present in 80% of bone-implant interfaces. (2 years f.u.).[72] 	<ul style="list-style-type: none"> - the highly conformal articular surfaces along with bicruciate retainment led to the so called “kinematic conflict”. [10,12] - lack of femoral flange.[73] - symmetrical femoral condyles. - too thin anterior bridges prone to fatigue breakage.[73] - lack of metal backing in tibial component. - symmetrical tibial plateaus. - poor tibial fixation components. - non-anatomical, symmetrical tibial component.



Figure 5: Geomedic Knee by Coventry and Averill.[21]

Duocondylar Knee, dr. John Insall, 1971

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
<p>The cemented Duocondylar knee was developed in 1971 by dr. Insall in collaboration with drs. Ranawat and Walker. This design could be seen as a full-fledged thin anterior union of two unicompartmental implants (Fig. 6,7).[12,13,57,74,75]</p>	<ul style="list-style-type: none"> - symmetrical design. - two Co-Cr femoral condylar components linked by a thin anterior bar. - pillars on the femoral side for fixation. - tibial tray constituted by two separate, high density PE, nearly flat pads, allowing kinematics freedom, opposed to Geomedic knee. <p>Subsequent modifications:[76,77]</p> <ul style="list-style-type: none"> - resurfacing of patellofemoral joint. - concave plateaus in the coronal plane to provide medio-lateral stability. - single piece PE tibial component. 	<ul style="list-style-type: none"> - poor ROM (102°), knee instability, symptoms related to patellofemoral joint, radiographic lucencies found in 76% of knees at 3 years (2-4 years f.u).[78] 	<ul style="list-style-type: none"> - lack of femoral flange. - thin anterior femoral bar prone to fatigue breakage. - two separate tibial components difficult to align and balance intraoperatively and easily subjected to misalignment after surgery. - lack of metal backing in tibial component. - symmetrical tibial plateaus. - poor tibial fixation components.



Figure 6: Duocondylar Knee by dr. Insall.[57]



Figure 7: The duocondylar prosthesis implanted. The retention of both ACL and PCL can be observed.[75]

UCI Knee, Waugh and Smith, 1971

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
<p>The UCI knee development began in February 1971, when dr. Smith and Waugh started working on a cemented anatomical condylar knee, specifically designed to retain cruciate ligaments and provide rotational freedom. Casting technique was employed for the manufacture of femoral and tibial components.[13,79,80]</p>	<ul style="list-style-type: none"> - symmetrical design. - multiple radii femoral component with no anterior femoral flange. - single piece, concave, horseshoe shaped, PE tibial tray. - underlying PE spikes for tibial fixation. 	<ul style="list-style-type: none"> - high prevalence (17.4%) of mechanical complications of the UCI Knee, including knee instability, tibial component loosening or deformation, and patellar problems (33 months f.u.).[81] - 27% of knees considered as failure. Implant instability, patellar dislocation and loosening of the tibial component represented the major complications (3-8 years f.u.). [82] 	<ul style="list-style-type: none"> - lack of femoral flange. - non-anatomical, symmetrical tibial component. - lack of metal backing in tibial component. - symmetrical tibial plateaus. - poor tibial fixation components. - insufficient stiffness and surface area of the 5.0 and 7.5-millimeter-thick tibial components leading to loosening and subsidence.[82]



Figure 8: UCI Knee by Waugh and Smith.[13]

Anatomical Total Knee (ATK), dr. Charles Townley, 1972

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
<p>1972 represents the birth of the Anatomical Total Knee, designed in Port Huron, Michigan, by dr. Townley (Fig. 9). This non conforming cemented BCR implant adopted a close to anatomy profile.[13,83-85] The first version provided only tibiofemoral replacement, while in 1973 a PE dome shaped patellar button was introduced, resulting in the first tricompartmental total knee prosthesis. Townley's Anatomical knee is now marketed as the Total Knee Original (Biopro, Port Huron, Mich), that will be discussed later on in this review.</p>	<ul style="list-style-type: none"> - cobalt-chrome (Co-Cr) femoral component with three radii of curvature in the sagittal plane, resulting in a polycentric geometry. - larger radius of curvature for the femur in the medio-lateral plane than in the anterior-posterior plane, broadening the contact area with the tibial component. - smaller radius of femoral condyle curvature in the sagittal plane to allow normal anterior-posterior displacement and non-constrained rotation. - extensive anterior femoral flange. - single piece PE tibial component with central cutout and cup-shaped concavities. - no intramedullary fixation pegs present on either femoral or tibial component. <p>Subsequent modifications[86]:</p> <ul style="list-style-type: none"> - PE dome shaped patellar button - porous-coated cementless option introduced. 	<ul style="list-style-type: none"> - poor ROM (>120° in only 12% of patients). Patellar dislocation and tibial loosening were the most frequent mechanical complications, although the incidence of the second was less than 2% (2 to 11 years f.u).[84] - high rates of pitting wear.[32] - hardly reproducible surgical technique (Townley made his own instruments).[87] 	<ul style="list-style-type: none"> - symmetrical femoral flange. - symmetrical femoral condyles. - lack of metal backing in tibial component. - symmetrical tibial plateaus. - poor tibial fixation components. - non-anatomical, symmetrical tibial component.

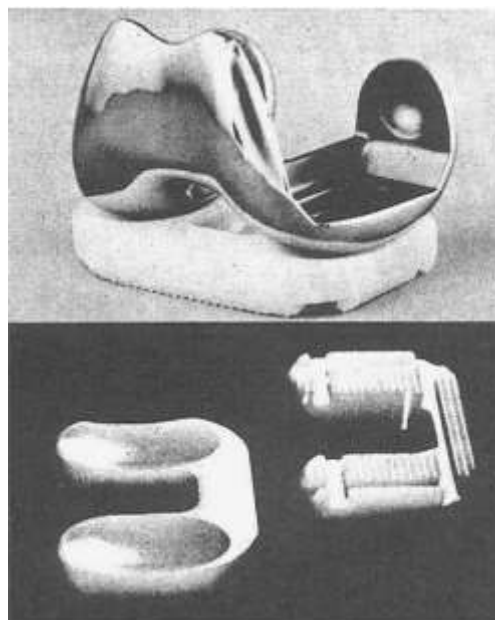


Figure 9: Anatomical Total Knee by dr. Charles Townley[13]

Leeds Knee, dr. Bahaa Seedhom, 1972

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
<p>In parallel with Townley, at the end of 1960s dr. Seedhom started working on a new anatomical TKA design, later called Leeds Knee (Fig. 10).[13,41,88,89] The Leeds knee was firstly implanted in 1972 and was utilized in four centers in England until 1984. Although the initial results were promising, no reports were published and the implant never received wide market adoption.</p>	<ul style="list-style-type: none"> - cobalt chrome femoral component with a 2 to 4 mm thickness. - single piece of solid-phase formed high density polyethylene tibial component. - asymmetrical femoral condyles flared posteriorly providing AP stability. - anatomical femoral flange. - curved internal surfaces of the femoral component in the attempt to minimize bone resection. - tibial implant made of two concave discs, joined by an anterior bridge. 	<ul style="list-style-type: none"> - lab tests demonstrated that the highly polished PE employed in this prosthesis resulted in wear rate of between 0.1 and 0.6 mm per year. Even in sedentary patients, this would lead to an implant lifetime of approximately 10 years.[89] 	<ul style="list-style-type: none"> - non-anatomical, symmetrical tibial component. - lack of metal backing in tibial component. - symmetrical tibial plateaus. - poor tibial fixation components. - thin anterior bridge prone to fatigue breakage.



Figure 10: Leeds Knee by dr. Seedhom.[13]

Hermes Knee, J.M. Cloutier, 1977.

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
<p>The first Cloutier’s design was the Hermes AC TKR (actual name Hermes 2C), developed in 1977 in Montreal.[90,91] The cemented design components were very similar to the modern BCR prosthesis.</p>	<ul style="list-style-type: none"> - titanium (Ti) femoral component with asymmetrical condyles, an enlarged notch and a deep trochlear groove. - two 7 mm thick independent carbon-reinforced PE inserts with a nearly flat surface, allowing for unconstrained motion. - U-shaped Ti tibial baseplate with two fixation pegs of 15 mm height. - dome shaped polyethylene patellar implant with a metal retainer with two 8 mm fixation pegs. <p>Subsequent modifications (Fig. 11):[33]</p> <ul style="list-style-type: none"> - shift from Ti to Co-Cr undertaken in order to avoid the high prevalence of metallosis and osteolysis associated to Ti implants. - increased coronal radius of curvature of femoral implant. 	<ul style="list-style-type: none"> - poor ROM (average 102.8°), encouraging but not optimal results in terms of kinematics (2 – 4,5 years f.u.).[90] - poor ROM (107 ± 12.6°).Four percent of the knees revised, including one loose femoral component and two for PE wear. Antero-posterior instability in 11% of the knees (10 years f.u).[91] - high incidence of revisions (18%), with the main causes being polyethylene wear, aseptic loosening and femorotibial instability. Mean flexion of 103° (80° to 120°) compared with a mean of 104° (10° to 130°) pre-operatively. Limited ROM and pain in 38% of patients (22 years f.u.).[33] 	<ul style="list-style-type: none"> - non-anatomical, symmetrical tibial component. - symmetrical flat tibial plateaus. - suboptimal tibial fixation components. - sharp cutout-cruciate interface.

	- shift from heat-press manufacturing of PE to compression molding PE.		
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Figure 11: Hermes 2C implant made of cobalt-chromium femoral and tibial components and 2 separate PE inserts.[33]

Oxford Knee, Goodfellow and O’Connor, 1976

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
The first design of the famous “Oxford Knee” was developed in 1976 by dr. Goodfellow and O’Connor and was implanted bicompartamentally (Fig. 12).[92] It exploited the same Gunston’s principle of two symmetrical unicompartmental devices, with retention of both ACL and PCL. In 1982 the bicompartament application was abandoned in favor of the unicompartmental one, as it is nowadays.	- two metal spherical femoral condyles. - two flat metal tibial components. - two separate concave mobile meniscal bearings of PE facing the femoral implant in a congruent way, without constraining the knee kinematics at the same time.[19,92,93]	- poor ROM (99°) and high incidence of bearing dislocation of Oxford Knee in ACL-deficient knees (2-6 years f.u.).[93] - excessive AP displacement during flexion.[32] - lack of adequate axial rotation.[32] - lack of a patellofemoral articulation.[32]	- separate tibio-femoral components difficult to align and balance intraoperatively and easily subjected to misalignment after surgery. - symmetrical tibial plateaus. - poor tibial fixation components. - lack of femoral flange. - single radius of curvature in femoral components.



Figure 12: The Oxford Knee, implanted bicompartamentally in a cadaveric sample.[21]

Low Contact Stresses (LCS) Knee, Buechel and Pappas, 1977

Brief description	Design features	Clinical limitations reported by studies in literature	Main design weaknesses
Influenced by a presentation of Goodfellow et al., dr. Buechel and Pappas started working on a new design, later called Low Contact Stresses (LCS) Knee system in 1977.[32,94,95] As the Oxford Knee, the LCS implant utilized mobile bearing surfaces to finally solve the orthopedic dilemma of congruency vs. constraint. Yet, the LCS TKA provided a total knee replacement instead of the two separate unicompartmental prosthesis of the Oxford one (Fig. 14). Within the LCS system a BCR solution with both cemented and cementless options was offered.	<ul style="list-style-type: none"> - metal femoral component. - metal U-shaped tibial baseplate. - two separate concave mobile meniscal bearings of PE. 	<ul style="list-style-type: none"> - significantly inferior survival of cemented BCR option with respect to the ACL sacrificing designs (12 years f.u.)[94] - similar ROM, but higher rate of tibial loosening, lower long term survivorship, and more challenging surgical technique for BCR arthroplasties rather than CR and rotating platform implants. Bearing related complications, including chronic instability, bearing subluxation, bearing dislocation, or bearing failure. (multicenter worldwide study, average 5.7 years f.u.)[96] 	<ul style="list-style-type: none"> - symmetrical femoral flange. - symmetrical femoral condyles. - suboptimal tibial fixation components. - symmetrical tibial plateaus. - non-anatomical, symmetrical tibial component. - sharp cutout-cruciate interface.



Figure 13: Bicruciate retaining LCS tibial metal baseplate and mobile PE bearings.[32]



Figure 14: Bicruciate retaining LCS prosthesis implanted in vivo.[32]

3. Modern BCR designs:

Total Knee Original (TKO), BioPro., 2018

The BioPro TKO prosthesis is the third generation of dr. Townley's Anatomical Total Knee (Fig. 15).[97] The main difference with the original design of 1972 lies in the tibial component, which is no more a single PE piece, but is constituted by a metal tibial tray and a single piece polyethylene insert, both horseshoe shaped to allow ACL and PCL retention. The multi-radius femoral component is made of cobalt-chromium, is porous coated on the proximal surface to enhance adherence to the bone and has two pins for stable fixation (Fig. 16). The TKO tibial insert is a single piece ultra-high molecular weight polyethylene (UHMWPE) with a symmetric and slightly dished proximal surface articulating with the resurfaced femoral condyles. This insert can have variable thickness (8-11 mm in a study by Pritchett[34]) and lies on a metal tibial baseplate made of titanium, with a porous coating facing the underlying bone. The medial and lateral aspects of the prosthesis are reinforced by a long inferior flange while two pegs and a small keel are used for fixation (Fig. 1). When needed, a dome-shaped PE patellar component, articulating with the asymmetrical trochlear groove, might be implanted.[34]

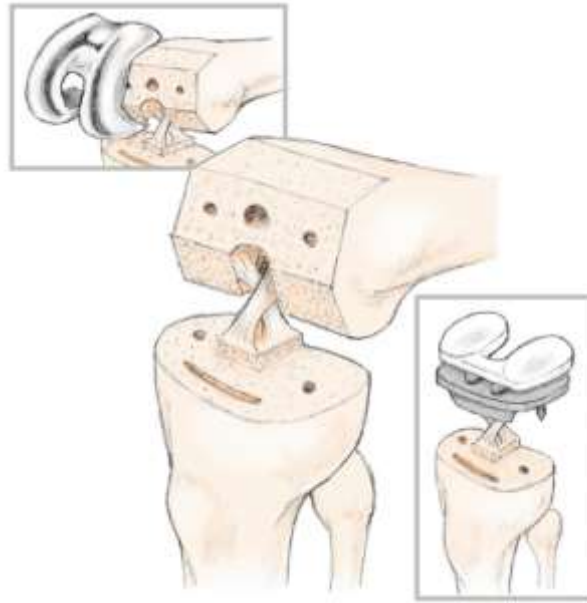


Figure 15: a schematic drawing of the BioPro TKO implant.[34]

Several studies were performed on this implant by dr. James Pritchett. A first one, compared the BioPro BCR prosthesis to a CR implant and showed better postoperative scores, kinematic performances and higher patient preferences for the ACL-sparing TKA rather than the ACL-substituting at 5 years after surgery at least.[28] The mean postoperative flexion was 119° for both groups. Subsequently, a 23-years follow-up study on a very close implant (Townley Anatomic, BioPro) revealed 89% survivorship, an increase of mean flexion from 104° preoperatively to 117° postoperatively.[34]

Out of 214 knees analyzed, 22 required revision, with the main reason being polyethylene wear. Femorotibial instability was seen twice. A 2015 study conducted by a collaboration between Massachusetts General Hospital and ETH Zurich reported crucial kinematic and design limitations of TKO implant.[98] In this research, dynamic simulations during a variety of daily activities revealed a non-restored differential medial and lateral rollback, seen in healthy knees. Even, the TKO prosthesis showed an abnormal and more posterior translation on the medial plateau than the lateral, contrasting with the medial pivot motion of knee during deep knee bend, demonstrated instead by the biomimetic BCR implant developed by the authors. These poor TKO performances are attributed to a non anatomical design of the tibial insert. Indeed, the symmetrical dished bearings do not reflect the medial concavity – lateral convexity of the normal tibial articular surface.

Especially, the decreasing slope in the lateral bearing results in a posteriorly directed joint force opposing to the anteriorly directed ACL pull, therefore also representing a possible cause for the high wear rate observed on the PE insert for such prosthesis. In contrast, a lateral convex bearing surface provides a leveled anterior portion, allowing a more anterior femoral location in extension, and a gradually increasing slope, encouraging normal posterior rollback with flexion.



Figure 16: The femoral component of TKO prosthesis with the porous coating on the inner surface [97]



Figure 17: Bottom view of the tibial baseplate (top left). Front view of the metal backed tibial component with PE symmetrical insert (top right). A radiograph of an inserted TKO implant (bottom) [97].

Vanguard XP, Zimmer Biomet, 2019

The modern Vanguard XP is the modified version of the well established Vanguard CR by Zimmer Biomet (Fig. 18,19).[99-101] While the patellofemoral joint is the same as in CR implant, the tibial component is significantly different, with a central cutout for the ACL attachment preservation. Since this is not allowing the employment of a central stem or a big keel, the cemented fixation is enhanced by two small pegs and two small keels on either side of the retained bone island.[102] The femoral component features asymmetric condyles to allow better kinematic. A funnel-shaped narrowed anterior femoral flange ensures low shear stresses on the patella.[21,36,103] Both femoral implant and tibial baseplate are made of forged Co-Cr. On the other side, the vitamin E-infused antioxidant polyethylene bearings are independently designed, one for the medial and one for the lateral plateau and incorporate compartment-specific geometries, recognizing the difference in kinematics between the medial and lateral side (Fig 18).[21]

Vanguard XP allows for different inserts thickness, with the lateral thicker than medial, making easier the ligament balancing.[21,102] 1 mm thickness increments represent another key feature of this implant.[104] Of high importance, it's possible to switch from the BCR to an ACL sacrificing solution intraoperatively. A considerable amount of short term studies on the contemporary Vanguard XP TKA have been performed, focusing on clinical results and kinematic outcomes. Lombardi et al. described intraoperative tibial eminence fracture as a major concern with this implant, that however could be minimized by targeted surgical technique modifications.[11] A case of implant instability and tibial loosening were reported too. Another study pinpointed higher operative times and higher number of complications related to Vanguard XP with respect to Vanguard CR.[102]

Aseptic tibial loosening was the major complication in the BCR group, with possible causes deemed suboptimal tibial component design and cementation technique. In particular, a two-stage process is suggested here. Similar results were showed by Christensen et al. in a comparative study of 66 BCR prosthesis at a minimum follow-up of 12 months.[105]

Higher frequency of reoperations and revisions was reported with aseptic tibial loosening being the main cause. Radiolucent lines were found in 30% of BCR patients. Although these poor results may reflect the initial learning curve of the surgeons with Vanguard XP, the subsequent 3-year follow up performed by Pelt et al. showed only fair survivorship of 88% with tibial loosening representing the most frequent complication.[106]

Knee flexion ROM improved from a preoperative mean of 121° to a postoperative mean of 123°. Concerns were finally related to traditional mechanical alignment technique that may result in joint stiffness and pain. On the other end, Alnachoukati et al. reported great patient reported satisfaction, function, and short-term (mean 12 months) outcomes for 146 patients receiving Vanguard XP prosthesis.[45] Special surgical instrumentation and third generation cementation technique were used in this research, but still one case of tibial loosening was reported. Mean postoperative ROM was 121°. Finally, kinematic studies on Vanguard XP design revealed contradictory results. While researches on this implant reported greater knee stability during gait and downhill walking[107], a better femoral component posterior offset ratio (lower femorotibial impingement in deep flexion)[108] and more natural screw-home mechanism in late extension[109] compared to CR TKA, other studies could show asymmetrical flexion-extension and internal-external rotation associated to Vanguard XP, indicating a still non-restored tibiofemoral kinematics.[110-112]



Figure 18: The modern Vanguard XP knee implant, side view[11]



Figure 19: The modern Vanguard XP knee implant, frontal view.[101]

Journey II XP, Smith & Nephew, 2016.

Journey II XP design was released on market in March 2016 by the american company Smith & Nephew (Fig 20,21).[9,47,53,113] This contemporary implant has been developed in the attempt to definitely solve all the major weaknesses of past ACL-sparing prosthesis. It aims to restore femorotibial joint line with an oblique three-degree angle and the shape of the asymmetrical joint surface.[114,47] For this reason, it

features asymmetric femoral condyles made of Oxinium™ (oxidized zirconium) articulating with a metal backed tibial component. The tibial baseplate is forged Ti-6Al-4V, that having a lower E modulus than CoCr reduces the risk of stress shielding and bone resorption. It is asymmetrically shaped with a more anterior position medially to better replicate the anatomical profile and ensure higher bone coverage and therefore lower implant loosening. The central notch is asymmetric as well, providing enough space for bicruciate preservation. Good fixation is given by a continuous keel and four pegs. The keel is angled posteriorly by 20° to allow fixation depth and contains grooves to improve implant cementation (Fig 22). Medial and lateral compartments are connected anteriorly by a reinforced bridge with increased thickness surrounding the cruciate notch that should prevent fatigue breakage. In order to have mismatched thicknesses between medial and lateral plateaus, two independent highly-crosslinked polyethylene (XLPE) bearings are used. They are designed with a medial concavity and lateral convexity with the aim to restore normal knee kinematic and tibiofemoral contact point through the ROM. During surgery, special instrumentation is used and finally the components are cemented separately. Upon cementation, the inserts are mated to the tibial tray by a fully captured lock detail with posterior and anterior locking interfaces. Like Vanguard XP, also Journey II XR allows for immediate intraoperative switch to ACL-sacrificing designs if the patient is no-longer a good candidate for BCR TKA.



Figure 20: the Journey II XR prosthesis by S&N.[113]



Figure 21: implanted Journey II XR TKA with retention of ACL and PCL.[9]

Laboratory tests revealed very promising results of Journey XP implant.[113] The tibial baseplate design completed fatigue testing at 500 lbs for 10 million cycles, which is more than double the 202 lbf minimum load recommended by ASTM F 2083-08 and the 225 lbs documented in the Zimmer Biomet literature around VANGUARD XP's fatigue strength. The Oxinium on XLPE material combination (Verilast™ technology) has proven no measurable wear at 6 million cycles, a significantly lower rate than Vanguard prosthesis. Tibial fixation testing reported a comparable outcome to short keel tibial designs, but significantly lower outcome than long keel implants, suggesting that further design adjustments may improve long-term clinical results. Given the recent market release, limited follow up studies are available in literature. An early experience with Journey II XR reported a mean 124° maximum flexion postoperatively, that however does not represent significant improvement from the mean 120° flexion preoperatively.[114] On top of that, a worse postoperative mean extension angle was found (2.3° post vs. -11° pre). Another preliminary study compared Journey II XR with a Journey II PCR TKA.[115] The BCR subjects revealed a higher overall flexion (128°) a closer to normal rollback than PCR ones through the knee flexion range. In alignment with these results, Arnout et al. reported that Journey II XR prosthesis can restore normal laxity through the knee ROM, compared to CR and PS implants.[24] However, another recent publication claimed that the kinematic results of Journey II XR are still far from the ones of UKA and healthy joint.[116] In particular, during early flexion, the medial side of BCR-TKA knees was significantly more anteriorly located than that of normal and UKA knees and the femoral external rotation angle of BCR-TKA knees was significantly greater than that of normal and UKA knees. Besides, from 30° to 120° of flexion, the lateral side of BCR-TKA knees was positioned more anteriorly than that of normal and UKA knees.

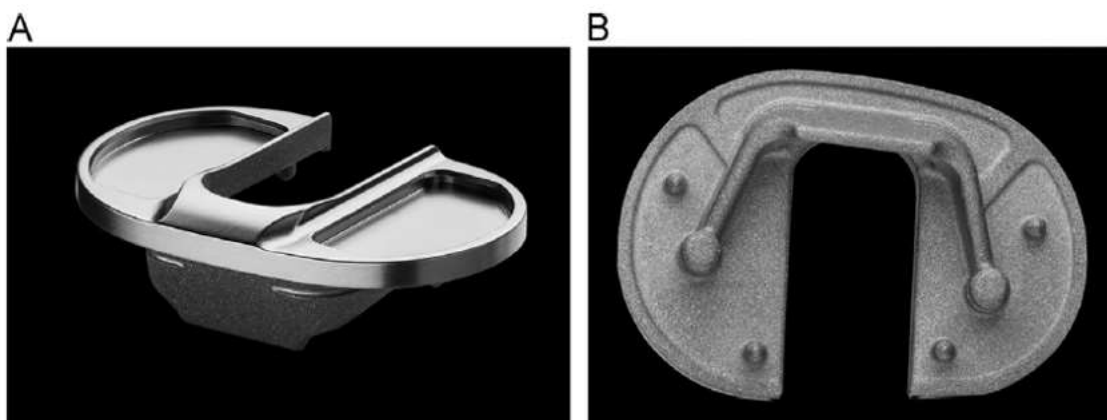


Figure 22: the forged Ti-6Al-4V tibial baseplate (A). Bottom view of the tibial component (B).[53]

4. Discussion

The historical BCR designs failed to successfully establish in the total knee replacement field. While the femoral component is almost identical to CR and PS designs, the tibial implant significantly differ from them, representing the major concern for BCR TKA. A recent study by dr. Ries et al. reported the main modes of failure of first-generation BCR designs being fracture of the anterior tibial bridge, insert dissociation, polyethylene wear and tibial component loosening.[46] All these complications are strictly interconnected and can be traced into suboptimal prosthetic design and insertion technique. Indeed, historical design flaws led to abnormal joint kinematics that univocally resulted in higher stresses on the implant, provoking early failures.[9] The kinematic conflict observed with Geomedic knee is a prime example. Learning the lesson form the past, contemporary BCR implants introduced substantial design changes that are believed to finally overcome the previous issues. However, short term clinical and kinematic results suggest that we are still far from ideality. The aim of this review is to list, describe and discuss all the main BCR designs that have ever been released on the market, along with their reported clinical outcomes. A special focus on limitations and weak points was done, in order to pinpoint the key aspects that a bicruciate implant should ideally feature for a durable and consistent TKA that could finally meet the ambitious expectations of young and active patients. Upon these considerations, an ideal BCR design should feature:

- Asymmetrical multi-radius femoral condyles with the medial bigger than the lateral to reproduce the knee anatomy.[9,10,39]
- Anatomical rather than deepened trochlear groove to allow physiological patellofemoral articulation.[39]
- The proximal surface of the femoral component including pins, grooves for stable cemented fixation or porous coating for cementless adhesion to the surrounding bone.[97]
- A metal backed tibial component to allow for modularity, higher implant strength and fixation along with reduction PE wear.[32,117]
- An anatomical metal baseplate with central cutout anatomically shaped, with asymmetrical profile.[73] This should not only include a more anterior position in the medial side of the connecting bridge, but also a bigger and more posterior medial plateau, like the Persona TM TKA by Zimmer

Biomet.[118-121] In this way a maximal bone coverage will be ensured, reducing the tibial loosening risk.[113]

- A thick and reinforced anterior tibial bridge made of a highly fatigue resistant biomaterial.[113]
- Back-surface of the metal tray featuring optimal cemented or cementless fixation components for a strong adhesion to the surrounding bone.
- A continuous anterior tibial keel with an oblique orientation is reputed to improve implant fixation[113], but revealed to be detrimental in cementless applications.[122,123]
- Two separate tibial inserts with the possibility to have higher lateral thickness than medial one (not in excess of 2 mm). This allows the surgeon to achieve a finer ligament balancing.[10,39]
- Insert thickness should not be lower than 8 mm to prevent high risks of wear and delamination/fractures.[117]
- Anatomical insert slopes, reproducing the medial concavity and lateral convexity seen in healthy knee. In this way, close to normal knee motion is expected.[10,47,98]
- A posterior bevel in the lateral insert which allows improved rollback and greater knee flexion.[39]

In addition to all these design features, important considerations must be taken regarding the locking mechanism, implant fixation, component materials, surgical technique and contraindications of BCR TKA.

A peripheral rather than central locking mechanism ensure lower rates of inserts dissociation to the tibial tray.[46] The fully capture lock detail implemented by Smith & Nephew shows promising outcomes in term of resistance to anterior lift-off.[113]

As already discussed bicruciate retaining arthroplasty is directed to patients with functionally intact cruciate ligaments, that inevitably are mostly represented by young people, with usually good bone structure. In such patients, a cementless fixation is recommended, as the rough and porous coated implant surface will stimulate bone ingrowth and both robust adhesion and integration within the strong surrounding tissues.[124] The side effects related to bone cement can be therefore avoided and durable implant fixation can be achieved.[60,124,125]

When coming to prosthetic materials, the literature shows that several different possibilities could be chosen with similar results. However, a few material combinations have proven to be objectively superior to others, in term of mechanical and biological reliability. For both femoral and tibial component, forged CoCr demonstrated to be a strong and biocompatible solution.[33,124] However, forged Ti-6Al-4V could represent a valid alternative, especially for the tibial implant, because of its close-to-bone elastic modulus, that dramatically reduce stress shielding, bone resorption and consequently implant loosening.[113] More technically complex biomaterials might also be utilized, like Oxinium.

Regarding the inserts, highly crosslinked polyethylene (HXLPE) constitutes the most attractive solution because of the extremely low wear rate compared to other polyethylene types. However it also features lower mechanical properties than UHMWPE, higher manufacture demands and therefore higher costs. Recently, Zimmer Biomet released a new proprietary polyethylene type called Vivacit-E HXLPE. The e-beam irradiation induced crosslinking and the grafted Vitamin E are the key aspects of this innovative material that showed exceptional oxidative stability, ultra-low wear, and improved mechanical strength during laboratory tests.[126]

A major concern linked to BCR TKA is the more challenging and less reproducible surgical technique compared to ACL-sacrificing arthroplasties. However, knee balancing and bone resection could be refined and significantly facilitated by modern “smart instruments”.[9,10] For instance, gyros may be exploited for tibial alignment, [127-129] sensor devices for the gap balancing and haptic surgical robotic guides for precise tibial resection, eliminating the risks of eminence undermining.[130]

Finally, the patient indications for bicruciate retaining TKR are getting stricter and stricter with modern designs, with dr. Tria et al. reporting that both cruciate ligaments must be intact; the deformity should not exceed 10° in any given plane; the range of motion must be at least 120° before surgery and the BMI should be less than [33.53] This is surely limiting the application of BCR implants to a narrow patient niche. New solutions to bypass or solve this restraint are needed and could represent a turning point, broadening the BCR eligible patients spectrum.

Conclusion

The retention of ACL and PCL in total knee arthroplasty is thought to be the key to finally bridge the gap with THA and fulfill the high expectations of young and active patients. Although BCR approach

demonstrated in several studies a more normal kinematics and proprioception and higher patient preferences, the commercial spreading of old BCR designs has been overwhelmed by the well established CR and PS implants, mostly because of critical design weaknesses and a more challenging surgical technique. Recently released BCR prosthesis attempt to overcome the past designs flaws. However, the early results suggest that the aim for a completely restored knee motion in BCR patients may not be definitely addressed yet and additional modifications might still be required. With increasing technologic and technical sophistication, we are getting closer and closer to the ideal TKA. Therefore, despite the huge challenges associated with bicruciate preservation, an ultimate prosthesis able to provide minimal tissue release, great postoperative performances and a quick return to daily-life activities and competitive sports could surely represent a motivating justification.

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